REMARKS

Claims 7 and 8 are currently pending in the application. Only claim 7 is in independent form.

Applicants wish to express their appreciation for the courtesies extended Applicants' representative, Amy E. Rinaldo, during a telephonic interview conducted on August 9, 2005.

Claims 7-9 stand rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. Specifically, the Office Action states that claim 7 recites "by comparing the markers obtained by said differential biopanning step to an array of known markers of disease," but there is no support in the specification for this limitation. In order to further prosecution, the claim has been amended to remove such language and alternative language has been included, such language having full support in the specification as originally filed.

With regard to claim 9, the Office Action has held that claim 9 recites "constructing a classifier using data from a template." In order to further prosecution, claim 9 has been canceled without prejudice, thereby rendering the present rejection moot. Reconsideration of the rejection is respectfully requested.

Claims 7-9 remain rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the enablement rejection.

The Office Action dated July 12, 2004, held that the claims contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertain, or with which it is most nearly connected, to make and/or use the invention.

Specifically, the Office Action dated July 12, 2004, held that the instant specification discloses that sera from both normal individuals and patients having ovarian cancer and phage display libraries expressing cDNAs of genes expressed in ovarian epithelial tumors and cell lines are used. The claimed method is then used for the identification of epitope-bearing phage clones displaying reactivity with antibodies in sera of patients with ovarian cancer but not in control sera. The claims

have been amended to more specifically recite that differential biopanning occurs between a control sera or test sera and the patient's sera. This is done to selectively biopan for markers of disease. These markers are epitope bearing clones as recited in claim 7. This method is disclosed on page 25, lines 5-page 26-21. This portion of the specification provides details with regard to the biopanning experiments and how such experiments correlate to the epitope bearing clones that are identified. Additional support for the claims as currently amended is provided in the examples of the specification as filed.

The portion of the specification referred to above provides details with regard to how the markers are identified. More specifically, the markers are identified because they are present in the cancer patients versus healthy sera. The fact that these markers are present in the cancer patients indicates that such markers are indicative of the presence of cancer and as such are cancer markers that can be used in an array. The array is a pattern or grouping of markers that is indicative of cancer. A single marker is not necessarily indicative of cancer. Many such markers are known to those of skill in the art and are however, the use of a single marker is not sufficient for use in detecting disease. Instead the presently claimed invention provides a method of creating an array of markers, or a combination of markers, that can be used to indicate the presence of cancer in patients. It is the combination of these markers that enables a more accurate analysis and identification of the presence of cancer in a patient. The attached abstracts indicate that p53 has been previously used as an indicator of breast cancer, however, the single marker is not sufficient for detecting cancer and instead there are large number of individuals who are not identified as having cancer. The combination or array of markers and method as recited in the presently pending claims provides for a more accurate analysis of the serum to determine the presence of cancer.

Further, the Office Action dated July 12, 2004, questioned how markers can be determined by automatic analysis. As stated in the specification at page 30, lines 16 through the end of page 31, the determination of what epitopes are

indicative of cancer can be automated. Such automation can occur by creating a program that analyzes the results of the differential biopanning and determines which epitopes reacted. Based on the above, and the amended claims it is respectfully submitted that the claims are supported by the specification as filed, and reconsideration of the rejection is respectfully requested.

Claim 9 stands rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicants regard as the invention. However, as claim 9 has been canceled without prejudice, this renders the present rejection moot and reconsideration of the rejection is respectfully requested.

It is well known in the prior art to biopan for a specific composition. For example, many ELISA assays are well known in the art and are used to detect various antibodies. However, there is no known assay currently available that will screen or create an array of markers that are accurate in diagnosing and staging cancer or other forms of disease. In other words, while the prior art biopanning methods can determine the presence of a single marker, there is no known method or assay that will screen for an unlimited number of markers within sera. The presently pending claims recite a method for detecting markers of disease. The purpose of the method is to use differential biopanning of normal patients and patients having the disease against a phage library in order to determine which markers are present in the disease state but are not present in the normal state. It is these limitless number of markers that are then used to create an array against which individuals suspected of having disease can be tested. This is not known or disclosed or suggested by any of the prior art currently available.

It is respectfully requested that the present amendment be entered in order to place the application in condition for allowance or at least in better condition for appeal. The application is placed in condition for allowance as it addresses and resolves each and every issue that remains pending. The amendments overcoming the rejections under 35 U.S.C. §112 are made exactly as suggested by the Office Action. The application is made at least in better condition for appeal as the amendment removes many issues thereby simplifying the issues on appeal. That is,

each and every rejection under 35 U.S.C. §112 has been overcome exactly as suggest in the Office Action. Further, the claims have been amended to more specifically define the invention while raising no new issues that would require any further searching. Rather, the amendments have been made in view of comments made in the Office Action that clearly distinguish the presently pending claims over the cited prior art. Hence, it is respectfully requested that the amendment be entered.

In conclusion, it is respectfully requested that the present amendment be entered in order to place the application in condition for allowance, which allowance is respectfully requested.

The Commissioner is authorized to charge any fee or credit any overpayment in connection with this communication to our Deposit Account No. 11-1449.

Respectfully submitted,

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